

1 **WILLIAMS & CONNOLLY LLP**  
2 Douglas R. Marvin  
3 Ana C. Reyes  
4 Paul E. Boehm  
5 725 Twelfth Street, N.W.  
6 Washington, DC 20005  
7 Telephone: (202) 434-5000  
8 E-mail: [dmarvin@wc.com](mailto:dmarvin@wc.com)  
9 E-mail: [areyes@wc.com](mailto:areyes@wc.com)  
10 E-mail: [pboehm@wc.com](mailto:pboehm@wc.com)

11 *Attorneys for Merck Sharp & Dohme  
12 Corp.*

13 **PEPPER HAMILTON LLP**

14 Nina M. Gussack  
15 Kenneth J. King  
16 3000 Two Logan Square East  
17 Eighteenth and Arch Streets  
18 Philadelphia, PA 19103  
19 Telephone: (215) 981-4000  
20 Email: [gussackn@pepperlaw.com](mailto:gussackn@pepperlaw.com)  
21 Email: [kingk@pepperlaw.com](mailto:kingk@pepperlaw.com)

22 *Attorneys for Eli Lilly and Company*

23 **UNITED STATES DISTRICT COURT**

24 **FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

25 **IN RE INCRETIN-BASED  
26 THERAPIES PRODUCTS LIABILITY  
27 LITIGATION**

28 Case No. 13md2452 AJB (MDD)

29 **DEFENDANTS' REPLY  
30 MEMORANDUM IN SUPPORT OF  
31 MOTION TO DISQUALIFY DR.  
32 ALEXANDER FLEMING AS AN  
33 EXPERT WITNESS FOR  
34 PLAINTIFFS**

35 Date: March 12, 2015

36 Time: 2:00 p.m.

37 Judge: Hon. Anthony J. Battaglia

38 Magistrate: Hon. Mitchell D. Dembin

39     ///

40     ///

41 Case No. 13md2452 AJB (MDD)

42 **DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISQUALIFY**

1 Plaintiffs concededly disclosed Defendants' confidential documents to Dr.  
 2 Alexander Fleming—an individual who founded and currently manages Exsulin, a  
 3 company that has developed and currently is testing in humans an anti-diabetes drug  
 4 designed to compete with the very medications at issue in this litigation. By failing to  
 5 provide Defendants with the advance notice expressly required by the Protective  
 6 Order, Plaintiffs denied Defendants the ability to object and to seek to prevent the  
 7 disclosure of this material to a competitor.

8 Plaintiffs should not be permitted to capitalize on their violation by continuing  
 9 to use Dr. Fleming as an expert in this litigation, and certainly not to opine on matters  
 10 related to the very confidential documents that improperly were provided to him by  
 11 Plaintiffs' counsel.

12 **ARGUMENT**

13 **A. Plaintiffs disclosed confidential discovery materials to Dr. Fleming in  
 14 clear violation of the Protective Order.**

15 There is no dispute that Plaintiffs knowingly and intentionally disclosed  
 16 confidential documents to Dr. Fleming without first providing Defendants notice of  
 17 their intention to do so. Opp. at 16. In failing to give Defendants the notice required  
 18 by the Protective Order, Plaintiffs deprived Defendants of the opportunity to object  
 19 and intervene. *Id.* at 16; ECF No. 564 (Am. Protective Order) ¶ 5(d).<sup>1</sup> Plaintiffs'  
 20 single-pronged defense hinges entirely on the faulty premise that Dr. Fleming is not a  
 21 "competitor": the disclosure did not technically violate the Protective Order, they say,  
 22 because Exsulin, the company that Dr. Fleming founded and presently leads as Chief  
 23 Executive and Chief Medical Officer, is only *testing* the diabetes treatment it has  
 24 developed, and has not yet received FDA approval to *market* the product. Opp. at 14.  
 25 Plaintiffs' contention is belied the meaning, including the regulatory definition, of the  
 26  
 27

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28 <sup>1</sup> Novo Nordisk, Inc. joins in the arguments set forth in this brief in addition to its  
 separately filed motion to disqualify Dr. Fleming, ECF No. 902.

1 term “manufacturer,” Exsulin’s own representations, and the clear terms of the  
 2 Protective Order.

3 First, Exsulin is plainly engaged in manufacturing as that term customarily is  
 4 understood.<sup>2</sup> FDA regulations expressly define “manufacturing” to include the  
 5 “**testing**” of prescription medication, including at “**any part of the process**.” 21  
 6 C.F.R. § 207.3(a)(8) (emphases added). Plaintiffs note that Exsulin is not currently  
 7 required to *register* with the FDA as a manufacturer, Opp. at 15, but that is only  
 8 because FDA regulations do not require that all manufacturers register: a company  
 9 “that **manufactures** its own drug for use in its clinical trial of the drug” is exempt  
 10 from registration. 71 Fed. Reg. 51276, 51284 (Aug. 29, 2006) (emphasis added).  
 11 That does not mean, of course, they are not manufacturers. To the contrary, the  
 12 regulations expressly indicate that companies *making and testing*, but not yet  
 13 marketing, products *are* manufacturers. Exsulin’s diabetes medication currently is in  
 14 Phase II clinical trials involving hundreds of patients in the United States and Canada.  
 15 See Exsulin, Investor Overview, *available at* <http://www.exsulin.com/investors2.html>  
 16 (last accessed Feb. 18, 2015). To state the obvious, Exsulin is manufacturing its  
 17 medication for use in those human clinical trials.

18 Second, Plaintiffs’ argument is inconsistent with Dr. Fleming’s own  
 19 representations about his company. Exsulin markets itself to investors, health  
 20

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21 <sup>2</sup> Notably, the dictionary broadly defines “manufacturer” as simply “one that  
 22 manufactures,” *i.e.*, one who makes something “from raw materials by hand or by  
 23 machinery” or who engages in “the act or process of producing something.”  
 24 *Merriam-Webster’s Collegiate Dictionary* 709 (10th ed. 1996); *see also American*  
*25 Heritage College Dictionary* 843 (4th ed. 2002) (same). Exsulin is plainly engaged in  
 26 “the act or process of producing” diabetes medication. *See also* Ronald W. Eades,  
*27 Jury Instructions on Products Liability* § 3.02.1 at 3-6 (LexisNexis, 4th ed. 2014) (“If  
 28 you are satisfied from the evidence that the defendant was involved in the design,  
 assembly, fabrication, production, construction or other preparation of the product, or  
 a component part of the product that is subject of this litigation prior to the sale of that  
 product to the user or consumer, then you will find that the defendant is a  
 manufacturer of that product.”).

1 professionals, and prospective patients as a ***manufacturer*** of prescription medication.  
 2 The company's website touts that “[f]or the last three years [E]xsulin's founders  
 3 operated 'under-the-radar' to achieve critical milestones in manufacturing,  
 4 formulation, animal studies, and clinical trial preparations.” Exsulin, Company  
 5 Overview, *available at* <http://www.exsulin.com/company.html> (last accessed Feb. 18,  
 6 2015). The website also states that Exsulin is dedicated to “the development *and*  
 7 *commercialization* of therapies that reverse the fundamental cause of diabetes,”  
 8 Exsulin, Home Page, *available at* <http://www.exsulin.com/> (last accessed Feb. 18,  
 9 2015) (emphasis added), and aims to market its product to 1.2 million patients in  
 10 North America alone, *see* Exsulin, Investor Overview, *available at*  
 11 <http://www.exsulin.com/investors2.html> (last accessed Feb. 18, 2015). It defies  
 12 common sense to suggest that Exsulin is not a competitor vis-à-vis Defendants.

13 Third, Plaintiffs' argument is inconsistent with the terms of the Protective Order  
 14 entered in this case. The Protective Order defines “competitor” as “***any manufacturer***  
 15 ***or seller*** of prescription medications other than the Producing Party, including,  
 16 without limitation, other Defendants in this Litigation.” ECF No. 564 (Am. Protective  
 17 Order) ¶ 5(d) (emphasis added). Plaintiffs' interpretation would render the Protective  
 18 Order's definition of “competitor” entirely redundant. *See Bayview Hunters Point*  
 19 *Community Advocates v. Metropolitan Transportation Comm'n*, 366 F.3d 692, 700  
 20 (9th Cir. 2004) (explaining that courts should avoid a construction “that would render  
 21 another part” of the contract “superfluous” (internal quotation marks omitted)). If a  
 22 company were a “manufacturer . . . of prescription medications” only if it were also a  
 23 “seller of prescription medications,” there would be no need for the Protective Order  
 24 to define “competitor” as “any manufacturer *or seller* of prescription medications.”  
 25 ECF No. 564 (Am. Protective Order) ¶ 5(d) (emphasis added).

26 **B. The Court should disqualify Dr. Fleming as an expert witness.**

27 Plaintiffs offer two arguments against disqualification. Neither has merit.

1       First, Plaintiffs argue that Defendants' motion is not timely. Opp. at 17. This  
 2 argument, however, fails from the start, as it arrives unaccompanied by any factual or  
 3 legal support. Motions for sanctions under Rule 37 are not subject to any express time  
 4 limit, and courts have rejected such motions as untimely only where there has been an  
 5 "unreasonable delay" in bringing the motion. *MGA Entertainment, Inc. v. Nat'l*  
 6 *Products Ltd.*, 2012 WL 4052023, at \*4 (C.D. Cal. Sept. 14, 2012) (collecting cases).  
 7 There has been no such delay here.

8       Plaintiffs disclosed Dr. Fleming as an expert witness on preemption on  
 9 November 24, 2014. Plaintiffs did not, however, disclose at that time that they  
 10 intended to divulge Defendants' confidential material to Dr. Fleming. Indeed, given  
 11 that expert discovery during this phase was to be limited to the issue of preemption,  
 12 Defendants had no reason to believe that Plaintiffs would ask Dr. Fleming to offer  
 13 wide-ranging opinions on a host of unrelated scientific and medical issues, many of  
 14 which extend far beyond his area of expertise. Notably, Defendants did *not* disclose  
 15 confidential material to their preemption expert for review in preparing his opening  
 16 report, but rather—consistent with their understanding of the Court's expectations—  
 17 asked their expert to focus on FDA policies and practices that shed light on FDA  
 18 statements related to the issue of preemption.

19       Defendants only learned that Plaintiffs disclosed confidential material to Dr.  
 20 Fleming on December 15, 2014, the day Plaintiffs served his 108-page opening report.  
 21 Defendants filed their motion to disqualify approximately one month later, on January  
 22 20, 2015. During the intervening month, a period that included the holiday season,  
 23 Defendants engaged in meet-and-confer efforts concerning Dr. Fleming's  
 24 disqualification with Plaintiffs' counsel in the MDL and the JCCP.<sup>3</sup> Defendants'  
 25 motion to disqualify Dr. Fleming was, if anything, relatively expeditious. And  
 26 Plaintiffs do not contend that they showed Dr. Fleming any additional confidential

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27       <sup>3</sup> Defendants notified the Court of their view that Plaintiffs violated the Protective  
 28 Order in their January 6, 2015, motion to strike and/or seal. See ECF Nos. 882, 883.

1 material between the time they served Dr. Fleming's report and Defendants filed their  
 2 motion to disqualify Dr. Fleming, or that they have otherwise been prejudiced by any  
 3 purported delay.

4 Plaintiffs do not cite any authority suggesting that a waiver arises in such  
 5 circumstances. Plaintiffs rely on *English Feedlot, Inc. v. Norden Labs, Inc.*, 833 F.  
 6 Supp. 1498 (D. Colo. 1993), but that case is inapposite. As an initial matter, *Feedlot*  
 7 concerned a motion for disqualification due to a prior confidential relationship; it  
 8 therefore did not apply the "unreasonable delay" standard under Rule 37. *Id.* at 1501.  
 9 Moreover, the district court in *Feedlot* found the motion untimely because the moving  
 10 party waited *over eight months* to file it and plainly filed it as a "mere tactical  
 11 maneuver." *Id.* at 1504. The case in no manner supports Plaintiffs' ambitious  
 12 proposition that the one-month period here constitutes an unreasonable delay. *See*  
 13 *also Gardner v. Toyota Motor Corp.*, 2010 WL 3733876, at \*4 n.1 (W.D. Wash. Sept.  
 14 1, 2010) ("The court finds that Toyota did not unreasonably delay its request for Rule  
 15 37 fees, given that the order granting the motion to compel was entered less than two  
 16 months before the motion for sanctions was filed.").

17 Second, Plaintiffs contend that their breach of the Protective Order was  
 18 harmless because the documents they disclosed to Dr. Fleming "include[d] no actual  
 19 trade secrets, like pricing data or manufacturing techniques." Opp. at 19. But there  
 20 can be no dispute that the confidential documents Plaintiffs' counsel provided to Dr.  
 21 Fleming contain sensitive discussions and reports concerning, *inter alia*, Defendants'  
 22 study designs and preliminary study results relating to the drugs at issue in this  
 23 litigation,<sup>4</sup> as well as twenty-one deposition transcripts of defense witnesses, *see*

24  
 25 <sup>4</sup> *See, e.g.*, MRKJAN0000205038; MRKJAN0000552189; MRKJAN0000930499;  
 26 MRKJAN10000281236. Indeed, Plaintiffs disclosed to Dr. Fleming numerous  
 27 documents designated *Attorneys' Eyes Only*—*i.e.*, documents so confidential that  
 28 defense counsel cannot even disclose them to their own clients. *See, e.g.*, Fleming  
 Expert Report, Appx. B (noting that Dr. Fleming reviewed MRKJAN0000892492,  
 MRKJAN0000930329, NOVO-01052171, AMYLN05278007, AMYLN05310370,  
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1 Fleming Report, Appx. B, at 12, all of which contain confidentiality designations.  
 2 One of the central purposes of a Protective Order in cases such as this is to prevent the  
 3 disclosure of this very type of information to Defendants' competitors, such as Dr.  
 4 Fleming, whose company is currently addressing “[c]omplicated safety and efficacy  
 5 issues” that are “closely related to those of the incretin drug products” with respect to  
 6 a drug that is intended to compete with Defendants' drugs. Fleming Report at 3.  
 7 Unfortunately, Dr. Fleming cannot unlearn this information—“[i]t is very difficult for  
 8 the human mind to compartmentalize and selectively suppress information once  
 9 learned, no matter how well-intentioned the effort may be to do so.” *BASF Corp. v.*  
 10 *United States*, 321 F. Supp. 2d 1373, 1380 (C.I.T. 2004) (internal quotation marks  
 11 omitted).

12 Plaintiffs' violation of the Protective Order is prejudicial because it prevented  
 13 Defendants from asserting a valid objection to the disclosure of their confidential  
 14 material to their competitor. *See* Mot. at 4-5. Put simply, the rights of notification  
 15 exist in the Protective Order to give Defendants the opportunity to object and have this  
 16 Court consider their objections *before* information is disclosed to a competitor. It is  
 17 not up to Plaintiffs to decide that Defendants would not have exercised this right or  
 18 this Court would not have granted their motion.

19 Defendants explained in their opening memorandum that a “crucial factor” in  
 20 determining whether a party may disclose confidential material to an expert who  
 21 works for a competitor is whether the expert is a “competitive decision-maker” at that  
 22 company. *Santella v. Grizzly Indus., Inc.*, 2012 WL 5399970, at \*4-5 (D. Or. Nov. 5,  
 23 2012). Plaintiffs are silent on this point, perhaps in recognition of Dr. Fleming's  
 24 capacity as Co-Founder, Chairman, and Chief Medical Officer of Exsulin. Dr.

25  
 26 and AMYLN05318927, which are designated “Attorneys' Eyes Only”). So as not to  
 27 burden the Court with another motion to seal, Defendants are not attaching these  
 28 documents as exhibits to this motion, but will provide copies to the Court upon  
 request.

1 Fleming plainly is “in a position to effectuate or direct decisions made using  
 2 knowledge that is tainted by [Defendants’] confidential information.” *Id.* at \*6  
 3 (internal quotation marks omitted); *see also Wang Laboratories, Inc. v. CFR*  
 4 *Associates, Inc.*, 125 F.R.D. 10, 13 (D. Mass. 1989) (good cause shown for preventing  
 5 disclosure of a party’s confidential documents to expert who admitted in his resume  
 6 that he currently consults with companies about competing products).

7 Likewise, Plaintiffs ignore authority that disqualification is an appropriate  
 8 sanction in such circumstances and fail to cite authority to the contrary. *See* Mot. at 5  
 9 (citing *Frazier v. Layne Christensen Co.*, 2005 WL 372253 (W.D. Wis. Feb. 11, 2005)  
 10 (Crocker, Mag. J.); *Irwin Seating Co. v. IBM*, 2007 WL 518866, at \*3 (W.D. Mich.  
 11 Feb. 15, 2007)). Plaintiffs’ disclosure of Defendants’ confidential material to their  
 12 competitor is a serious violation of an order entered by this Court, and it warrants Dr.  
 13 Fleming’s disqualification.

14 **C. At a minimum, the Court should strike portions of Dr. Fleming’s  
 15 report that refer to or rely upon confidential discovery materials.**

16 In their opening memorandum, Defendants argued that if the Court does not  
 17 strike Dr. Fleming as an expert witness, the Court should strike the portions of Dr.  
 18 Fleming’s report that rely on or reference confidential material disclosed to Dr.  
 19 Fleming in violation of the Protective Order. Mot. at 5-6. Plaintiffs do not dispute  
 20 that striking these portions of the report would be an appropriate remedy for Plaintiffs’  
 21 violation. Accordingly, at a minimum, the Court should strike these portions of the  
 22 report as a sanction for Plaintiffs’ clear violation of the Protective Order.

23 **CONCLUSION**

24 For the reasons stated above, Defendants respectfully request that the Court  
 25 disqualify Dr. Fleming from serving as an expert witness for Plaintiffs in this  
 26 litigation and strike his preemption expert report in its entirety, or in the alternative,  
 27 provide the equitable relief this Court deems appropriate, including but not limited to  
 28

1 striking the sections of his report that rely upon confidential material submitted to Dr.  
2 Fleming in violation of the Protective Order.

3  
4 Dated: February 18, 2015

By: s/ Paul E. Boehm

5 Attorney for Merck Sharp & Dohme Corp.  
6 E-mail: pboehm@wc.com

7 By: s/ Amy J. Laurendeau

8 Attorney for Amylin Pharmaceuticals, LLC  
9 E-mail: alaurendeau@omm.com

10 By: s/ Kenneth J. King

11 Attorney for Eli Lilly and Company, a  
12 Corporation  
13 E-mail: kingk@pepperlaw.com

14  
15 **SIGNATURE ATTESTATION**

16 I hereby certify that authorization for the filing of this document has been  
17 obtained from each of the other signatories shown above and that all signatories  
18 concur in the filing's content.

19 By: s/ Paul E. Boehm

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